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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,363	05/25/2001	Dirk M. Anderson	2852-E	4679

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[REDACTED] EXAMINER

O HARA, EILEEN B

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 09/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/865,363	ANDERSON ET AL.
	Examiner	Art Unit
	Eileen B. O'Hara	1646

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36-41 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Claims 36-41 are pending and under consideration in the instant application. Claims 1-35 have been canceled and claims 36-41 have been added as requested by Applicant in the preliminary amendment, Paper Number 3, filed May 25, 2001.

All claims are currently under examination.

Priority

2. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 09/577,780. A statement reading “(now U.S. Patent No. 6,419,929)” should be included after “USSN 09/577,780, filed May 24, 2000” as the first sentence of the specification.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68. The oath does not claim priority to Application 09/577,780, and does not claim priority to Application 08/995,659 under 35 U.S.C. § 120, under which it should, and improperly claims benefit under 35 U.S.C. § 120 to the provisional applications, which should claim benefit under 35 U.S.C. § 119(e).

Specification

4.1 The disclosure is objected to because of the following informalities: in the sequence listing, SEQ ID NOS: 10 and 12 are nucleic acid sequences and SEQ ID NOS: 11 and 13 are amino acid sequences, but in the specification on page 5, lines 17-19 and lines 28-33, SEQ ID NOS: 10 and 12 are identified as amino acid sequences. These should be corrected, as well as any other incorrect recitations of sequence identifiers elsewhere in the specification.

Appropriate correction is required.

4.2 The abstract of the disclosure is objected to because it does not pertain to the claimed invention. Correction is required. See MPEP § 608.01(b).

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The deletion of Figures 4 and 5 in the preliminary amendment has been approved by the Examiner, and when Applicants submit formal drawings, only Figures 1-3 should be submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 38 and 41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using antibodies to the polypeptide of SEQ ID NOS: 13 and 11 or for antibodies to polypeptides encoded by a nucleic acid that is capable of hybridizing under stringent conditions to a DNA having a nucleotide sequence of the complement of the sequences shown in SEQ ID NOS: 12 or 10, does not reasonably provide enablement for antibodies to polypeptides encoded by nucleic acids capable of hybridizing under stringent conditions to a DNA having a nucleotide sequence of the sequence shown in SEQ ID NOS: 12 or 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification discloses two polypeptides having the amino acid sequences of SEQ ID NOS: 13 and 11, which are human and murine RANKL proteins, respectively, and which have the specific activities of binding to and activating the RANK receptor, and which are encoded by the nucleic acid sequences of SEQ ID NOS: 12 and 10, respectively, and antibodies to these proteins. Variant polypeptides encoded by nucleic acid molecules that hybridize to the complements of SEQ ID NOS: 12 and 10 under the stringent conditions recited would be enabled if they have the same activity as the polypeptides of SEQ ID NOS: 13 and 11; however the claims do not recite any activity of these variant polypeptides, so that these variant

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polypeptides might not be able to bind to the RANK receptor, for example, and are therefore not enabled. Recitation of a function at the end of the claims, such as “wherein the polypeptide binds RANK”, would overcome this part of the rejection.

Antibodies to polypeptides encoded by nucleic acid molecules that hybridize to the complements of SEQ ID NOS: 12 and 10 under the stringent conditions recited and that have an activity of the polypeptides of SEQ ID NOS: 13 and 11 are enabled, since these nucleic acids would be highly similar to the coding strands shown in SEQ ID NOS: 12 and 10 and would encode proteins that would be highly similar to the polypeptides of SEQ ID NOS: 13 and 11, and therefore the antibodies to these proteins would also be highly similar and would bind to the proteins of SEQ ID NOS: 12 and 11. However, nucleic acid molecules that hybridize to the nucleic acid sequences (coding strands) shown in SEQ ID NOS: 12 and 10, would encode completely different proteins from those of SEQ ID NOS: 13 and 11, and therefore antibodies to those proteins would not bind to the proteins of SEQ ID NOS: 13 and 11, and the specification has not taught one of ordinary skill in the art how to use antibodies that don't bind to the proteins of SEQ ID NOS: 13 and 11. Additionally, as written, the claims encompass polypeptides encoded by extremely small fragments of nucleic acid molecules capable of hybridizing to the complement of SEQ ID NOS: 12 and 10, which would not necessarily elicit an immune response. These rejections would be overcome if in part g) of the claims if they were changed from “hybridizing under stringent conditions to a DNA having a nucleotide sequence as shown in SEQ ID NO: 12 (10) or its complement, wherein stringent conditions....” to “...hybridizing under stringent conditions to the **full complement** of a DNA having a nucleotide sequence as shown in SEQ ID NO: 12 (10), wherein stringent conditions....”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 36-41 are indefinite because claims 36 and 39 encompass an antibody that is “is immunoreactive”, and it is not clear what activities are included in this term. This rejection would be overcome by replacing “is immunoreactive” with “binds”.

Conclusion

- 8.1 No claim is allowed.
- 8.2 Antibodies to the polypeptides of SEQ ID NOS: 11 and 13 are free of the prior art.

The art considered pertinent to the present application is Boyle, WO 98/46751, Oct. 22, 1998 (cited by Applicant), which discloses a polypeptide identified as human osteoprotegerin, which is 100% identical to the polypeptide of SEQ ID NO: 13 of the present application. This is **not considered** prior art, because the date of publication is after the priority date of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR
PRIMARY EXAMINER